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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,158	08/01/2001	Yong Hua Zhu	LOMAU.138A	7213

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EXAMINER

ROBERTS, PAUL A

ART UNIT PAPER NUMBER

3731

DATE MAILED: 10/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/921,158	ZHU, YONG HUA	
	Examiner	Art Unit	
	Paul A Roberts	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 27-45 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-9 and 46-49 is/are allowed.
- 6) ☒ Claim(s) 10-12, 14-19 and 50-52 is/are rejected.
- 7) ☒ Claim(s) 13, 20-26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 27-45 are withdrawn from consideration as being drawn to a non-elected invention. Claims 1-26, and 46-52 are currently pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 10, 11, 12, 14-19, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Myers et al. "Myers" US 5,486,195. Myers discloses a method of closing a blood vessel wound comprising locating the wound (the device is placed within the wound); positioning a surgical implement (78) so that a portion of the implement extends through the wound and a portion extends out of the wound (figure 8); providing a hemostatic material (22d); positioning the hemostatic material about the implement (when the material is placed into the wound it is positioned about the outer surface of the implement); and advancing the hemostatic material over the surgical implement so that the hemostatic material is disposed adjacent the wound (this step occurs as the materials flows out of the element 36).
3. Regarding claim 11, an access passage to the wound is provided by element 50.
4. Regarding claim 12, the access passage is provided by a plurality of elongate retractor arms (element 50 has a plurality [two] retractor arms.)

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5. Regarding claim 13, the retractor clears a field surrounding the wound prior to positioning the hemostatic material.
6. Regarding claim 14, hemostatic material is held in place on the wound as the material becomes at least partially soaked with blood from the wound.
7. Regarding claims 15 and 16, the surgical implement comprises a guidewire (shown in figure 8) and an elongate catheter.
8. Regarding claim 17, a tip of the catheter is extends through the wound (see figure 8).
9. Regarding claim 18, the catheter is removed from the wound after the hemostatic material is disposed adjacent the wound (see column 11, line 66).
10. Regarding claim 19, the hemostatic material comprises a sponge-like material comprising a hemostatic agent (Myers describes the material as being gelatinous. Gelatinous is taken to be within the scope of 'sponge-like').
11. Regarding claim 50, the surgical instrument flexes the edges of the blood vessel when it is placed within the wound.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers in view of Janzen et al. "Janzen" 6325789. Myers discloses all of claim 10, but does not disclose

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that the hemostatic material should contain a blood clotting agents. Adding blood clotting agents to hemostatic punctures sealers is very well known in the art. Fibrin glue is often added or used as the sole hemostatic material. Janzen discloses the use of fibrin glue. The motivation to use this glue is that it helps clots the blood as well as retard the flow of blood in the area. At the time of the invention it would have been obvious to one having ordinary skill in the art to substitute the fibrin glue sealant of Janzen for the sealant of Myers because the Janzen sealant helps the blood clot faster than non-clot enhancing sealants, and clotting helps promote hemostasis. Figure 8 shows that the hemostatic material does not enter the wound, but rests on top of the wound site.

Allowable Subject Matter

Claims 1-9, and 46-49 are allowed. The following is an examiner's statement of reasons for allowance: The cited prior art does anticipate claim 1. Particularly, Myers et al. does not anticipate a method of providing a tool that has a catheter, guidewire, retractor, a hemostatic material wherein the material is advanced over the outer surface of the catheter. 'Over' is taken to mean the catheter goes through the material, because there is no support in specification for the method of placing the material above the catheter.

Claims 13, 20-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: the cited prior does not disclose a hemostatic material that is poked by the surgical instrument, inter alia. Regarding claim 22, one would not 'apply' an adhesive (such

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as fibrin glue) to the adhesive material disclosed by Myers. There is no pushrod disclosed by Myer that goes around the catheter. There is no obvious reason to add a pushrod to the catheter since the Myer device has alternate means to move the hemostatic material.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 2002/0156495 discloses the use of applying pressure to a wound site to aid hemostasis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts
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02/10/03


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